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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---|---------------------|------------------|
| 10/673,650 | 09/29/2003 | Wilhelmus Petrus Martinus Maria van Erp | CRD5049-US-NP | 2353 |
| 27777 | 7590 | 10/19/2006 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | MEHTA, BHISMA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3767 | |

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/673,650 | Applicant(s) VAN ERP ET AL. | |
| | Examiner Bhisma Mehta | Art Unit 3767 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1-10 are objected to because of the following informalities: In line 6 of claim 1, the word "guidewire" needs to be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith (U.S. 5,217,482). In Figure 5, Keith shows a rapid-exchange catheter comprising a stainless steel hypotube (22B), an inner tubular body (80B), and an outer tubular body (82B). The hypotube has a proximal tubular portion, an intermediate tubular portion (117) having a longitudinal indentation (72B), and a distal portion (74B). The proximal portion of the hypotube is cylindrical. The distal portion of the hypotube extends into the outer tubular body. In lines 37-65 of column 8, Keith teaches that it is desirable to provide a transition in flexibility between the tubular portions of the hypotube to the inner and outer tubular bodies. The inner tubular body has a proximal guidewire port, a distal guidewire port, and a guidewire lumen (52) which extends between the ports. In lines 37-62 of column 7, Keith teaches sealing the proximal end of the outer tubular portion (82) to the hypotube (66) with a single seal and sealing the

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proximal end of the inner tubular portion (80) to the hypotube (66) with a single seal adjacent the bonding region (74) as shown in Figure 2. Figure 2 also shows an inflation lumen (62 and 104) which extends through the proximal and intermediate tubular portions of the hypotube and through the annular space between the inner and outer tubular bodies into the interior of a balloon (26). The proximal collar (36) and the distal collar (40) of the balloon are affixed to the inner and outer tubular bodies. In lines 26-30 of column 10, Keith teaches the hypotube as being a single tubular shaft. With regards to claims 4 and 5, the distal portion of the hypotube has an arcuate cross-section (72B) and the longitudinal portion of the hypotube is shallower in the proximal direction and deeper in the distal direction as shown at 68B in Figure 5.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith discloses a rapid-exchange balloon catheter as claimed. Even though Keith teaches that it is desirable to provide a transition in flexibility between the tubular portions of the hypotube to the inner and outer tubular bodies, Keith does not teach a tapering portion between the proximal cylindrical portion and the indented intermediate portion. In Figure 5, Ressemann et al show a rapid-exchange balloon catheter with a

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stainless steel hypotube (23) having a tapering portion between an proximal cylindrical portion (32) and an indented intermediate portion (68) and teach that it is desirable for a catheter to have a relatively stiff proximal portion and a relatively flexible distal portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of Keith to include a tapering portion between the proximal cylindrical portion and the indented intermediate portion as taught by Ressemann et al to provide more flexibility to the catheter thus allowing it to be more easily guided to a desired body location.

Even though Keith teaches using a balloon catheter in angioplasty procedures, Keith does not specifically teach the catheter having a stent crimped around the balloon. In lines 19-26 of column 4, Ressemann et al teach that it is well known that the components of the rapid-exchange balloon catheter as disclosed could also be used on other catheters such as stent delivery catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a stent on the balloon catheter of Keith as both Keith and Ressemann et al disclose using balloon catheters for angioplasty procedures and Ressemann et al teach that stent delivery catheters are well known in the art of angioplasty procedures.

Response to Arguments

6. Applicant's arguments filed August 17th 2006 have been fully considered but they are not persuasive. In response to applicant's argument that the distal portion (74B) as disclosed by Keith does not provide "a transition in flexibility between the tubular

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portions of the hypotube to the inner and outer bodies”, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Keith clearly discloses the hypotube as having a distal portion (74B) which extends a distance into the outer tubular body as seen in Figure 5. Applicant's argument that distal portion (74B) is both tubular and indented is further unclear as claim 1 is drawn to the hypotube having a distal portion and Keith shows a hypotube with a distal portion (74B). Finally, claim 1 does not specifically recite what is providing “a transition in flexibility between the tubular portions of the hypotube to the inner and outer bodies”; it merely indicates that a transition in flexibility is provided.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

